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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,519	09/27/2000	Bruce W. Gibbs	BC-0256-P02	2122

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GAMBRO, INC  
PATENT DEPARTMENT  
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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/672,519

**Applicant(s)**

GIBBS, BRUCE W.

**Examiner**

Patricia M Bianco

**Art Unit**

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2&4. 6) ☒ Other: *Detailed Action*.

Art Unit: 3762

## **DETAILED ACTION**

### ***Election/Restrictions***

The restriction set forth in paper no 5 has been withdrawn after reconsideration.

All claims in the instant application (claims 1-11) have been examined on the merits at this time.

### ***Information Disclosure Statement***

The information disclosure statement filed 12/22/00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No copies of the references listed on the IDS filed 12/22/00 were submitted with the form PTO-1449.

The examiner has reviewed all US Patents listed on pages 1 & 2 so these references have been considered at this time and need not be resubmitted. However, the listed Foreign Patents or Published Applications on page 3 and the Other Documents listed on pages 3 & 4 have not been considered at this time. Copies of these documents should be resubmitted if Applicant desires that they be considered at the time of the next action.

Art Unit: 3762

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Keller et al. (6,200,287). Keller discloses an apheresis system and method wherein the system includes a disposable preconnected cassette assembly as well as a number of tubing assemblies (20/50/60/80/90/100) interconnected thereto. Tubing assembly (20/60) is a blood inlet/return and blood component return assembly. A blood processing vessel (352), i.e. centrifuge, is interconnected to the tubing assemblies and cassette. A red blood cell collection assembly is connected to the cassette for receiving separated red blood cells and comprises a collection bag (950). Keller further teaches that selective filtering may be desired to remove white blood cells. For example, leukoreduction may be desired to reduce any likelihood of febrile non-hemolytic transfusion reactions. If such leukoreduction is deemed appropriate, the red blood cell/storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag (954) through a filter and into a new storage bag. A plasma collection bag (94) and a platelet collection bag (84) are connected to the cassette assembly via tubing. During use, blood is removed from a patient or donor, separated into components, including

Art Unit: 3762

RBC, platelets, and plasma, using a centrifuge vessel using the pre-connected disposable system and red blood cell collection assembly. The components, including RBC, plasma and platelets, are stored in their respective containers. Keller also teaches that the RBC may pass through a leukocyte filter before being finally stored. Keller also discloses that the RBC collection tubing assembly further includes a sterile barrier filter/drip spike assembly (956). Also, a storage solution may be added that advantageously facilitate storage of the RBCs for a longer period of time than without storage solution. The solution may be contained in a separate storage solution bag that can be selectively interconnected to the RBC collection bag. Such selective interconnection may be provided via sterile-docking tubing utilizing a sterile connecting device, such as by the sterile barrier filter/drip spike assembly. The use of assembly facilitates the maintenance of a closed system, thereby effectively avoiding bacterial contamination. Since Keller discloses that the leukocyte filter is used to provide leukoreduction and that the red blood cell/storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag (954) through a filter and into a new storage bag, it is implicit that the system will have a filter connected to a RBC storage reservoir or bag. This filtration is inherently done after centrifugation. Further, since a storage solution would be added to the final RBC storage bag or reservoir, and is taught to be connected to the bag via the barrier/spike and storage solution, it would inherently be placed between the centrifuge and leukoreduction filter to achieve the desired leukocyte free product. See figures 1, 2A & 2B as well as the entire disclosure.

Art Unit: 3762

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. ('287). Keller et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the air removal bag is interconnected to the RBC storage bag. Keller does disclose the use of an air removal tubing segment (100) including an air removal bag (104) that is connected to the cassette assembly for receiving air from the cassette assembly and the centrifuge during priming. It would have been obvious at the time of the invention to connect the air removal bag to the RBC storage bag to remove air therefrom, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claims 3, 4 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. ('287) in view of Minshall et al. (5,009,654). Keller et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically the use of frangible connectors in the tubing between the leukoreduction filter and RBC collection bag. Keller does teach of selective interconnection being

Art Unit: 3762

provided via sterile-docking tubing utilizing a sterile connecting device, such as by the sterile barrier filter/drip spike assembly.

Minshall discloses a tubing assembly that is a closed apheresis kit or circuit containing tubing and bags connected. It is also taught that the tubing may include normally-closed frangible connectors in the flow path of each portion to keep the circuit sterile. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the tubing of Keller to include frangible connectors in the tubing between the filter and collection bag to keep the pathway sterile, since Keller suggests the use of an assembly that is a closed system to effectively avoiding bacterial contamination.

### ***Conclusion***

Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After Final communications.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

pmb   
November 24, 2003